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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,825	03/07/2002	Kevin J. McKernan	12130-009001	3375
26161	7590	12/15/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			AKHAVAN, RAMIN	
			ART UNIT	PAPER NUMBER
			1636	
DATE MAILED: 12/15/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/092,825	MCKERNAN ET AL.	
	Examiner	Art Unit	
	Ramin (Ray) Akhavan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1-83.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-83 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-83 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-83 are pending and under consideration in this action.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-2, 4-69 and 71-83, drawn to a yeast two-hybrid assay method to identify sequences for interacting proteins conducted, classified in class 435, subclass 4.
- II. Claims 1, 3, 4-83, drawn to a bacterial two-hybrid assay method to identify sequences for interacting proteins, classified in class 435, subclass 4.

At the outset, it should be noted that claims 1, 24, 71 and 74 link inventions in group I and II. The restriction requirement for the linked inventions is subject to the nonallowance of the linking claim(s), claims 1, 24, 71 and 74. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The claims encompass two separate inventions based on the critical aspect of the claimed method being conducted in yeast versus bacterial host cells. As such the inventions in Groups I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions a two-hybrid assay using yeast as host cells clearly cannot be used concomitantly with other host cells, such as bacteria. For example, in a mating type yeast two-hybrid, the plurality of bait constructs are transformed into one haploid cell while the plurality of prey constructs are transformed into another haploid cell, with subsequent mating. Therefore, one could not mix and match yeast and bacterial systems. Additional distinguishing elements or characteristics that evidence a materially different mode of operation, for example, include the type of bait/vector constructs, the type of reporter genes used, the size of vector molecules.

For example the commonly used GAL4 bait and prey construct would simply not work in bacterial cells, while the bacterial two-hybrid systems comprising bacterial repressors/activators would not be utilized in yeast cells. Furthermore, reporter markers that are based on amino acid selection in yeast (e.g. URA or TRP selection) could not be used in bacterial cells. Alternatively, a commonly used AraC/LexA-based bacterial two-hybrid system would simply be inoperable in a yeast system. In addition, there is nothing in the disclosure or the art to contravene the foregoing basis for rejection or that would indicate that two-hybrid assays conducted in yeast or bacterial host cells are interchangeable. Indeed, there are additional distinguishing characteristics between the two systems.

For example, generally bacterial cells grow much faster than yeast cells and can be transformed with higher efficiency, thus providing better coverage in library-based screens. Furthermore, as yeast systems would often involve additional steps where library constructs are passed through bacteria, using a bacterial system would obviate such additional steps. Moreover, depending on the library being screened, eukaryotic regulatory proteins (e.g. cell cycle components) could be toxic in yeast by interacting with yeast homologs, which would be unlikely in bacterial systems. Of course, by the same token, heterologous proteins expressed in bacteria may also be toxic for reasons other than functionality. In addition, yeast systems would require nuclear localization of the hybrid proteins and the localization signal for other cellular compartments could prevent a bait or prey from reaching the nucleus, an issue that would not arise in bacterial systems. In sum, for the foregoing reasons a bacterial and yeast two-hybrid systems would require distinct elements, steps and compositions that would not be interchangeable between the two inventions, thus biologically and patentably distinguishing the two inventions.

Furthermore, searching for bacterial two-hybrid methods would not necessarily be co-extensive with a search for yeast two-hybrid methods. Each group would require a separate search, thus restriction for examination purposes as indicated is proper. Applicant is advised that a reply to this restriction requirement must include an election for the invention (i.e. Group I or II) to be examined, for the reply to be complete, notwithstanding that the requirement be traversed (37 CFR 1.143). Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if none or more of the currently named inventors is no longer an inventor of at least one claim remaining

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in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

The claims encompass two distinct inventions, thus restriction is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Akhavan whose telephone number is 571-272-0766. The examiner can normally be reached between 8:30-5:00, Monday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD, can be reached on 571-272-0781. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300 for regular communications and 703-872-9307 for After Final communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully submitted,

Ray Akhavan/AU 1636


GERRY LEFFERS
PRIMARY EXAMINER